

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

BAGLY, <i>et al.</i> ,)	
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)	
Plaintiffs,)	
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)	
v.)	C.A. No. 20-cv-11297-PBS
)	
UNITED STATES DEPARTMENT)	
OF HEALTH AND HUMAN SERVICES,)	
<i>et al.</i> ,)	
)	
Defendants.)	
)	

**RESPONSE TO PLAINTIFFS' OPPORTUNITY TO SUPPLEMENT THE RECORD IN
SUPPORT OF THEIR STANDING**

As the Government has explained, the Department of Health and Human Services is reconsidering the challenged rule and intends to engage in a new rulemaking to ensure that the Section 1557 regulations are consistent with the Biden Administration’s commitment to equity and to expanding access to coverage and care for underserved communities. Nevertheless, federal courts have jurisdiction to resolve legal disputes over agency rulemakings only if the plaintiffs can demonstrate standing as of the date they filed suit. At this point, almost all of the rule challenged in this case has been in effect for nearly a year. But Plaintiffs have not been able to demonstrate how the rule has resulted in cognizable injury to them—or how injury was imminent when they filed suit. In their supplemental filing dated June 17, 2021, Plaintiffs seek almost exclusively to rely upon the experiences of nonparty participants in the healthcare system, without demonstrating the necessary link to an injury to Plaintiffs themselves. The only Plaintiff offering any evidence of *some* concrete injury that was imminent at the outset of the litigation in July 2020 is Indigenous Women Rising (“IWR”), but IWR fails to carry its burden to demonstrate that it suffered an injury caused by the 2020 Rule that can be redressed by the relief it seeks. There is thus no occasion for the Court to consider the merits of Plaintiffs’ challenge.

I. BACKGROUND AND LEGAL STANDARDS

On June 19, 2020, the United States Department of Health and Human Services (“HHS”) promulgated a final rule making modifying regulations implementing Section 1557 of the Affordable Care Act. *See Nondiscrimination in Health and Health Programs or Activities, Delegation of Authority*, 85 Fed. Reg. 37,160 (June 19, 2020) (“2020 Rule”). The effective date of these modifications was August 18, 2020. *Id.*

Between August and October 2020, two district courts enjoined several provisions of the 2020 Rule from taking effect. *See Asapansa-Johnson Walker v. Azar*, 480 F. Supp. 3d 417 (E.D.N.Y. Aug. 17, 2020) (staying the 2020 Rule’s repeal of the Section 1557 regulatory definition of discrimination “on the basis of sex”); Order, *Whitman-Walker Clinic, Inc. v. HHS*, No. 1:20-cv-01630-JEB, ECF No. 55 (D.D.C. Sept. 2, 2020) (enjoining enforcement of the 2020 Rule’s incorporation of the religious exemption contained in Title IX into Section 1557 regulations and of the repeal of the definition of “on the basis of sex” insofar as it includes discrimination on the basis of sex stereotyping); *Asapansa-Johnson Walker v. Azar*, No. 1:20-cv-02834-FB-SMG, 2020 WL 6363970 (E.D.N.Y. Oct. 29, 2020) (staying “the repeal of 45 C.F.R. § 92.206,” which requires covered entities to treat individuals consistent with their gender identity).

The balance of the 2020 Rule went into effect on August 18, 2020, including a modification to the scope of entities subject to Section 1557, the repeal of former 45 C.F.R. § 92.207’s explicit examples of discriminatory practices in the provision and administration of health related insurance and replacement with a general prohibition on discrimination, modifications to legal standards for enforcement of Section 1557 violations, modifications to the standards regarding meaningful access to programs or activities by limited English proficient persons, a determination not to take a position by rule regarding whether Section 1557 encompasses discrimination on the basis of association, and conforming amendments to related regulations. In their Amended Complaint, Plaintiffs challenged *all* of the 2020 Rule’s modifications to Section 1557 regulations. Recognizing that the allegations in their Amended Complaint alone were insufficient to support

their standing, Plaintiffs filed thirteen evidentiary declarations in support of their standing on November 18, 2020, *see* ECF No. 27, “much as they would for a summary judgment motion,” *see Torres-Negron v. J&N Records, LLC*, 504 F.3d 151, 163 (1st Cir. 2007). Introducing that evidence converted the Rule 12(b)(1) motion into a factual one and forfeited any argument on Plaintiffs’ part that the Court’s subject matter jurisdiction inquiry should be limited to the four corners of their Amended Complaint. *See id.* at 163 (explaining that “the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case” on a Rule 12(b)(1) motion) (quotation omitted).

Recognizing that “common sense dictates that a court can and should consider the activities of the plaintiff during and after the time that the complaint is filed in order to assess [how imminent an alleged] future injury” was at the outset of the litigation, *see Nat’l Sec. Couns. v. CIA*, 898 F. Supp. 2d 233, 262 (D.D.C. 2012), on June 3, 2021, the Court permitted Plaintiffs an opportunity to supplement the record, including through submission of concrete evidence to substantiate their allegations of injuries imminent in July 2020. *See* Transcript of Hearing on Defendants’ Motion to Dismiss (hereinafter “Mot. Hr’g Tr.”) at 78:19-19; *see also id.* at 44:24-25 (“I think they are claiming imminent injury. It’s just they felt precluded from supplementing.”). Plaintiffs submitted additional evidence on June 17, 2021, *see* ECF No. 56, when most of the challenged provisions of the 2020 Rule had been “effective . . . for about [ten] months. . . . [D]uring those [ten] months, it was possible to measure any injury to the [Plaintiffs’] interests” or “measure projected future injury” that was allegedly imminent at the outset of the litigation. *See Massachusetts v. HHS*, 923 F.3d 209, 219 (1st Cir. 2019).

II. PLAINTIFFS’ SUPPLEMENTAL MATERIALS CONFIRM THEY LACK STANDING

Plaintiffs’ submissions lack evidence to substantiate their allegations that they faced imminent harm in July 2020 traceable to the 2020 Rule. Because “[a]llegations of possible future injury” are not sufficient, *see Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409 (2013) (quotation

and emphasis omitted), Plaintiffs’ speculation in the Amended Complaint did not plausibly allege standing, *see United States v. AVX Corp.*, 962 F.2d 108, 115, 116-17 (1st Cir. 1992). And Plaintiffs’ failure to produce any concrete evidence to substantiate their speculation of imminent harm—now that most of the regulation has been in effect for nearly a year—makes clear that they did not face concrete, particularized, and personal imminent injury stemming from the regulatory provisions that they sought to challenge. *See Equal Rights Ctr. v. Post Props., Inc.*, 633 F.3d 1136, 1141-42 (D.C. Cir. 2011) (denying *Havens* standing where plaintiff did “not spell out when it engaged in” the alleged “counteraction programs” which would have had to be “actual or imminent at the time it filed suit”). On the now-supplemented record, “the extent to which the challenged [provisions] . . . perceptibly impede the plaintiffs’ mission-orientated activities [still] seems difficult to measure, or, in other words, are imperceptible.” *See Nat’l Fair Hous. All. v. Carson*, 330 F. Supp. 3d 14, 46 (D.D.C. 2018).¹

Defendants agree with Plaintiffs that “the Court should analyze their standing as of the time of the filing of the complaint.” ECF No. 56 at 1. But no Plaintiff alleged an actual or ongoing injury due to any provision of the challenged regulation at that time. Instead, the parties dispute whether any Plaintiff faced an *imminent* injury due to each of HHS’s 2020 changes to its Section 1557 regulations at that time. *See* ECF No. 27 at 9.²

¹ In *Equal Means Equal v. Ferriero*, --- F.4d ---, 2021 WL 2659061 (1st Cir. June 29, 2021), the First Circuit recently held that “an organization cannot establish [*Havens*] standing . . . when the service impaired is pure issue advocacy,” nor can an organization “adopt a mission so that the organization expressed an interest in the subject matter of the case, and then spend its way into having standing.” *Id.* at *4 (first quoting *PETA v. U.S. Dep’t of Ag.*, 797 F.3d 1087, 1093-94 (D.C. Cir. 2015) and then quoting *Blunt v. Lower Merion Sch. Dist.*, 767 F.3d 247, 288 (3d Cir. 2014)). That holding undermines the organizational Plaintiffs’ advocacy-related injuries here.

² The Supreme Court analyzes the standing inquiry based on the time “when the suit was filed.” *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 569 n.4 (1992); *see also Friends of the Earth, Inc. v. Laidlaw Env. Servs. Inc.*, 528 U.S. 167, 180 (2000) (“we have an obligation to assure ourselves that [plaintiff] had Article III standing at the outset of the litigation”). But it is immaterial whether the inquiry focuses at the time of the original Complaint or the Amended Complaint here.

Although the legal standard looks to the date of the complaint, “common sense dictates that a court can and should consider the activities of the plaintiff during and after the time that the complaint is filed in order to assess [how imminent] such a future injury” was at the outset of the litigation. *See Nat'l Sec. Couns.*, 898 F. Supp. 2d at 262. And during the past ten months, “it was possible to measure any injury to the [Plaintiffs’] interests” or “measure projected future injury” in July 2020. *See Massachusetts*, 923 F.3d at 219. But Plaintiffs have been unable to show, with evidence, that they faced anything more than speculative future injury at the outset of the litigation.

Plaintiff CrescentCare highlights this broader failure. Plaintiffs have argued that CrescentCare has standing to press its claims that HHS invalidly and arbitrarily construed the term “health program or activity” in Section 1557 (resulting in a narrower scope of covered entities). Plaintiffs did not allege that CrescentCare had suffered ongoing injury due to this construction by the time of the Amended Complaint. *See* ECF No. 27 at 28. Instead, they claimed that the provision “will reduce the reimbursements that Plaintiff Healthcare Facilities will receive for the care that they provide” at a future time. *See* ECF No. 27 at 26 (citing Am. Compl. ¶¶ 237, 241) (emphasis added). Plaintiffs submitted evidence from two declarants associated with CrescentCare with personal knowledge of the organization’s operations—Alice Riener and Noel Twilbeck—both dated November 17, 2020. ECF No. 27-7 at p. 13 (“Riener Decl.”), ECF No. 27-12 at p. 18. By that time, the rule had been in effect for three months, but neither declaration included concrete facts demonstrating that CrescentCare had experienced the reduction in reimbursements that it had alleged as imminent in July 2020. Instead, Riener merely asserted that the rule “will also cause CrescentCare to lose revenue” at some hypothetical future time. *See* Riener Decl. ¶ 18 (emphasis added); *see also id.* ¶¶ 19-21. Finally, after the Court invited CrescentCare to supplement the record with concrete evidence of actual or ongoing injuries, on June 17, 2021, after the rule had been in effect for about ten months, CrescentCare submitted no evidence that it has experienced or is experiencing the feared reduction in typical reimbursements. CrescentCare’s alleged injuries were not imminent at the outset of the litigation; if the injuries had been imminent, Plaintiffs would

have suffered injury—and introduced evidence to that effect—from some point over the past ten months.

The other Plaintiffs’ efforts to establish standing to challenge each of the 2020 Rule’s provisions fail for similar reasons. The Court should therefore dismiss the Amended Complaint for lack of standing.

A. The Keith Declaration and Associated Materials are Not Evidence of any Plaintiff’s Injury, Let Alone One Fairly Traceable to Anything in the 2020 Rule

Without evidence that particular Plaintiffs have experienced actual injuries, Plaintiffs seek to rely on data about the industry as a whole. Plaintiffs submitted one organization’s analysis of “1,386 silver marketplace [insurance] plan options from 176 insurers in the 36 states that use HealthCare.gov.” (“Out2Enroll Report”). *See Declaration of Katie Keith ¶ 10, ECF No 51-1 (“Keith Decl.”).* The analysis reports that four of these insurers—Bright Health, United Healthcare, Alliance, and MercyCare—include a benefit design that the report describes as including “broad” transgender-related exclusions for thirteen 2021 silver marketplace plans in eight states. *See ECF No. 56-1 at 14-15.*³ But Plaintiffs have failed to show *personal* injury from any of these four insurers’ plans: there is no evidence that any Plaintiff has experienced or is experiencing a decrease in reimbursement as a result of any of these four insurers’ policies. And Plaintiffs have not demonstrated that it is substantially likely that any of these plans’ transgender subscribers will turn to any of the particular Plaintiff organizations for uncompensated care—instead of taking no action or some other action—in such numbers as to perceptibly impair the Plaintiff organizations’ ability to provide services. Indeed, no Plaintiff “serves as the [default] ‘secondary payor’” for gender-affirming care for any transgender subscribers of any of these four insurers. *See Massachusetts, 923 F.3d at 218.*

Even if Plaintiffs had made the necessary showing of injury, they haven’t made the equally necessary showing of a direct nexus between these policies and any aspect of the 2020 Rule.

³ In order to illuminate the record for comparison purposes, Defendants attach the 2020 Marketplace Plan Compliance with Section 1557 Out2Enroll Report as Exhibit 1.

Because the Out2Enroll Report only analyzes silver marketplace plans, Plaintiffs have not carried their burden to “identify, articulate, and substantiate” their theory of how the Report provides evidence to support their standing to challenge the 2020 Rule’s construction of the scope of covered entities.⁴ *See Nat’l Exch. Carrier Ass’n v. FCC*, 253 F.3d 1, 4 (D.C. Cir. 2001).

Moreover, because Plaintiffs have not demonstrated that these benefit designs are permissible under the 2020 Rule in light of the Supreme Court’s landmark decision in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), Plaintiffs have failed to demonstrate a concrete causal link between these four insurers’ benefit designs and the 2020 Rule’s replacement of former 45 C.F.R. § 92.207’s explicit examples of discriminatory health insurance practices with a general prohibition on discrimination. Even assuming that the 2020 Rule “had ‘encouraged’” these benefit designs, Plaintiffs do not establish causation as a matter of Article III standing. *See Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41-42 (1976). “The text of the 2020 Rule prohibits discrimination on the grounds prohibited by Title IX,” *see Washington v. HHS*, 482 F. Supp. 3d 1104, 1114, (W.D. Wash. 2020), and HHS explained that the 2020 Rule did not “preclude application of the [Supreme] Court’s construction” of civil rights statutes as prohibiting gender identity discrimination, 85 Fed. Reg. at 37,168; *see also* 84 Fed. Reg. at 27,857 (declining to take certain policy positions by rule “[b]ecause of the likelihood that the Supreme Court will be

⁴ Section 1557 covers “any health program or activity, any part of which is receiving Federal Financial assistance, including credits, subsidies, or contracts of insurance[.]” 42 U.S.C. § 18116(a). The 2020 Rule construed this provision to govern certain entities providing healthcare and “an entity principally or otherwise engaged in the business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing healthcare.” 85 Fed. Reg. at 37,244-45 (42 C.F.R. § 92.3(b)-(c)). But Section 1557 also covers “any program or activity that is administered by an Executive Agency or any entity established under [Title I of the ACA].” 42 U.S.C. § 18116(a).

The Out2Enroll report relates to silver marketplace plans offered “in the individual market in states that use Healthcare.gov.” *See* Keith Decl. ¶ 7, ECF No. 56-1. “These plans remain subject to [the 2020 Rule] because they are sold on the Exchanges established under Title I of the ACA (*see* § 92.3(a)(3) of this final rule).” *See* 85 Fed. Reg. at 37,170; *see also id.* at 37,174 (Qualified Health Plans “would be covered by the rule because it is a program or activity administered by an entity established under Title I (i.e., an Exchange), pursuant to § 92.3(a)(3).”).

addressing the issue in the near future”). Consistent with the preamble language and President Biden’s Executive Order 13988, on May 10, 2021, HHS issued a Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments Act of 1972. *See* ECF No. 50. In that Notification, HHS explained that the HHS Office for Civil Rights (“OCR”) “will interpret and enforce Section 1557’s prohibition on discrimination on the basis of sex to include: (1) discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity. This interpretation will guide OCR in processing complaints and conducting investigations[,]” including those in covered benefit designs. *See id.* at 3.

B. The Cited Cigna Policy is Not Evidence of any Plaintiff’s Injury, Let Alone One Fairly Traceable to Anything in the 2020 Rule

Plaintiffs’ argument fares no better with respect to their discussion of Cigna as a “prominent example of an insurance company that has [purportedly] changed coverage policies.” ECF No. 56 at 2. This alleged change does not establish standing. First, Plaintiffs have not shown that Cigna’s purported change is harming them in any way. Plaintiffs assert that they have “patients enrolled in Cigna plans.” *See* ECF No. 56 at 4 & n.3. But even if they have Cigna patients, Plaintiffs have failed to show that Cigna patients (1) will seek from them the type of surgical care purportedly excluded, and (2) that such care will be uncompensated. That Plaintiffs might some day have to provide uncompensated care to a Cigna subscriber “without any description of concrete plans, or indeed even any specification of *when* the some day will be—do[es] not support a finding of the ‘actual or imminent’ injury that [Supreme Court] cases require.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 564 (1992).

Indeed, Plaintiffs can only speculate that the Cigna plan limits coverage for any Plaintiff’s hypothetical future patients in light of the exceptive language Cigna uses. Specifically, Cigna’s

2021 Medical Coverage Policy explains that “some benefit plans may expressly cover some or all of the procedures listed below for gender reassignment surgery.”⁵

Second, even if Plaintiffs had made the necessary showing of injury, they haven’t made the equally necessary showing of a direct nexus between the Cigna policy and any aspect of the 2020 Rule. Plaintiffs provide no evidence that these benefit designs are policy choices that have been taken *because* of anything in the 2020 Rule. *See Massachusetts*, 923 F.3d at 224 n.9. A copy of Cigna’s policy on treatment for gender dysphoria with an effective date of April 2018 appears to include a similar benefit design, suggesting that Cigna included it “even before” the 2020 Rule, *see id.*; *see also* Medical Coverage Policy: Treatment of Gender Dysphoria, Cigna 4 (April 15, 2018) (attached as Exhibit 2).

An examination of the cited Cigna policy document shows that it provides coverage for significant types of gender affirming care. For example, it covers gender reassignment surgery procedures, including female to male reconstructive genital surgery, female to male reconstructive chest surgery, male to female reconstructive chest surgery, and male to female reconstructive genital surgery. *See* 2021 Cigna Policy at 3-4. Plaintiffs fail to explain how Cigna’s current coverage for gender affirming care is fairly traceable to the 2020 Rule. Plaintiffs cannot establish causation merely by pointing to the 2016 Rule because that rule explicitly allowed for benefit designs not to cover all medically necessary health services related to gender transition: under the 2016 Rule (and the 2020 Rule) covered insurance “issuers are not required to cover all medically necessary services. Moreover, [HHS] do[es] not affirmatively require covered entities to cover any particular treatment[.]” Nondiscrimination in Health Programs and Activities, Final Rule, 81 Fed. Reg. 31,376 31,435 (May 18, 2016). In the 2016 Rule’s preamble, HHS “reject[ed] commenters’ suggestion that the rule require[s] covered entities to provide coverage for all medically necessary health services related to gender transition regardless of the scope of their coverage for other

⁵ Medical Coverage Policy: Treatment of Gender Dysphoria, Cigna 4 (May 18, 2021), available at <https://perma.cc/UY3K-KNXG> (“2021 Cigna Policy”).

conditions.” *Id.* The former explicit “prohibition in § 92.207(b)(4) on categorically limiting coverage for all health services related to gender transition is intended to prevent issuers from placing categorical, arbitrary limitations or restrictions on coverage for *all* gender transition-related services, such as by singling out services related to gender transition for higher co-pays; it is not intended to prevent issuers from placing nondiscriminatory limitations or restrictions on coverage under the plan.” *Id.* (emphasis added).

To be sure, the failure to cover such services must be “evidence-based and nondiscriminatory,” *id.*, but Plaintiffs have not attempted to meet their burden in establishing those as faults with the Cigna policy.

In sum, Plaintiffs have not shown that Cigna made substantive changes to its benefit design in light of the 2020 Rule. And as a result, they also have not shown that Cigna would likely change its benefit design if this Court issued an order vacating the 2020 Rule’s construction of the scope of covered entities or its replacement of 45 C.F.R. § 92.207 with a general prohibition on discrimination. Plaintiffs therefore have not shown that such an order would likely redress any plausible injury that might be caused by Cigna’s benefit design. *See California v. Texas*, 141 S. Ct. 2104, 2115 (2021).

C. Evidence that Two Insurers Provide Taglines in Spanish, Tagalog, Chinese, and Navajo is Not Evidence of any Plaintiff’s Injury and Undermines Plaintiffs’ Standing Arguments

No Plaintiff has provided any evidence substantiating a claim of *personal* imminent harm at the outset of the litigation in July 2020 due to the 2020 Rule’s modifications to the standards regarding meaningful access to programs or activities by limited English proficient persons. For example, in September 2020, Plaintiff CrescentCare alleged that the 2020 Rule “will [imminently] burden the resources of the organizations that provide healthcare to . . . [limited English proficient (“LEP”)] people.” Am. Compl. ¶ 242. *See* ECF No. 27 at 37. In November 2020, a CrescentCare declarant speculated that the rule “will cause CrescentCare financial harm through an increase in non-reimbursable costs” at some hypothetical future time. *See* Riener Decl. ¶ 20 (cited at ECF No.

27 at 37). In lieu of concrete evidence to substantiate those assertions, Plaintiffs submitted evidence of two insurers—one in Alabama and one in Arkansas—that continue to provide taglines⁶ in their summaries of benefits only in Spanish, Tagalog, Chinese, and Navajo. *See ECF No. 56 at 4-5* (citing *Arkansas Blue Cross and Blue Shield: Silver Plan 1 PPO Summary of Benefits and Coverage* (2021), available at <https://perma.cc/T2CJ-HVTF>; *Bright Health: Silver 4200 Summary of Benefits of Coverage* (2021), available at <https://perma.cc/P3BG-MKQ9>).

But whether New Orleans-based CrescentCare serves an unspecified number of patients from Arkansas and Alabama, *id.* at 5, “is simply not enough” to “support a finding of the ‘actual or imminent’ injury that [is] require[d].” *Lujan*, 504 U.S. at 564. CrescentCare has not provided evidence to demonstrate that (1) subscribers of these Alabama and Arkansas insurers are turning to it for care, (2) those subscribers are LEP, (3) those subscribers speak languages other than Spanish, Tagalog, Chinese, and Navajo, (4) those subscribers are likely encountering difficulties because they lack a tagline in their language, (5) these insurers are not likely compensating CrescentCare for their subscribers’ care and (6) those subscribers exist in sufficient numbers to perceptibly impair CrescentCare’s ability to provide services. CrescentCare’s “generalities” leave these matters “open to surmise” and “cannot survive a motion to dismiss.” *See AVX Corp.*, 962 F.2d at 117.⁷

⁶ Taglines are “short statements written in non-English languages that indicate the availability of language assistance services free of charge.” 81 Fed. Reg. at 31,468 (former 45 C.F.R. § 92.4).

⁷ Although Plaintiffs’ two cited insurers no longer appear to provide the notice of nondiscrimination in the cited communications, the record is silent as to the manner in which these insurers may continue to provide the notice to consumers. They continue to post the notice on their website along with other important notices. *See* <https://www.arkansasbluecross.com/> (link to “Non-discrimination notice” in bottom-left corner); https://www.arkansasbluecross.com/docs/librariesprovider6/member-forms/other-forms/non-discrimination-notice.pdf?sfvrsn=acd179fd_0 (Non-Discrimination Notice); <https://brighthealthcare.com/individual-and-family/resource/care-partners/al-bbpa> (link to “Notice of Nondiscrimination” at bottom under “Individual Resources”); <https://cdn1.brighthealthplan.com/docs/commercial-resources/2021-section-1557-notice.pdf> (Non-Discrimination Notice). But they may also include it in other mailings to their subscribers.

D. IWR’s Injuries are Not Fairly Traceable to any Provision of the 2020 Rule

IWR is the only Plaintiff to provide evidence that in the ten months since the 2020 Rule took effect, it allegedly experienced some injury that was arguably imminent at the outset of the litigation. Specifically, IWR provides statements about an increase in funding requests to its Abortion Fund, which it states has never turned away a client due to lack of funds. Declaration of Rachael Lorenzo ¶¶ 3, 7, ECF No. 56-2 (“Second Lorenzo Decl.”). But IWR has “failed to show how this injury is directly traceable to” the 2020 Rule’s construction of the scope of entities covered by Section 1557. *See California*, 141 S. Ct. at 2117.

The only facts Plaintiffs provide about why IWR is receiving increased calls do not relate to increased Abortion Fund expenditures;⁸ IWR Co-Founder Lorenzo states that “[s]ome callers” who are merely asking for “basic information about abortion care and pregnancy options . . . report that [the Indian Health Service (“IHS”)] and other providers refuse to give them the information that they need to access an abortion.” Second Lorenzo Decl. ¶ 5. But IHS has not changed any policy or practice as a result of the changes in the 2020 Rule implementing Section 1557 of the ACA, *see Declaration of Dr. Greggory Woitte (“Woitte Decl.”) ¶¶ 7-11* (attached as Exhibit 3), and Plaintiffs provide no evidence that other formerly covered entities associated with IWR’s callers have changed a policy or practice in light of the 2020 Rule’s modifications to the scope of covered entities. Finally, Plaintiffs provide no evidence that any such policy change is, in turn, responsible for the increased Abortion Fund expenditures. Nothing in the 2016 Rule required covered entities to provide notice about abortion care and pregnancy options.⁹

⁸ IWR provides no evidence that the increased call volume itself—now only about ten callers in a week—has “perceptibly impaired [its] ability to provide . . . services.” *See Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982). Only the significantly increased Abortion Fund expenditures could arguably be considered such a perceptive impairment “with the consequent drain on the organization’s resources” required to distinguish the interest from IWR’s “abstract social interests[.]” *See id.*; *see also Equal Means Equal*, --- F.4d ---, 2021 WL 2659061, at *4.

⁹ The 2016 Rule’s Notice Requirements, formally codified at 45 C.F.R. § 92.8, can be found at 81 Fed. Reg. 31,469

The information Plaintiffs have provided does not indicate that the 2020 Rule has led more persons to seek IWR services. IWR offers Abortion Fund grant “recipients many benefits that have nothing to do with” anything that would stem from IHS’s status as a covered entity under Section 1557 of the ACA. *See California*, 141 S. Ct. at 2117. “IWR’s Abortion Fund helps Indigenous people pay for abortion care by paying clinics for a portion of the procedure and by providing [IWR] clients the necessary funds to cover lodging, gas, food, childcare, and other related travel expenses.” Declaration of Rachael Lorenzo ¶ 4, ECF No. 27-6 (“First Lorenzo Decl.”). “Given these benefits, neither logic nor intuition suggests that the [mere] presence” of HHS’s new regulation excluding IHS from the scope of covered entities “would lead an individual to [seek funding from IWR] programs that its absence would lead them to ignore.” *See California*, 141 S. Ct. at 2118. Moreover, “IWR’s Abortion Fund is open to all Indigenous people in the United States and Canada who . . . are seeking an abortion in the United States” and IWR makes no effort to account for the likelihood that state policies or other factors that have nothing to do with the 2020 Rule are driving the increased demand for IWR’s funding services. *See* First Lorenzo Decl. ¶ 4. Indeed, a major global pandemic has been taking place throughout the last year which itself has reduced access to healthcare services while healthcare providers have been overwhelmed with COVID-19 patients. *See, e.g.*, Declaration of Ellen LaPointe ¶ 29, ECF No. 27-4. “It would require far stronger evidence than [IWR] has offered here to support their counterintuitive theory of standing, which rests on a ‘highly attenuated chain of possibilities.’” *California*, 141 S. Ct. at 2119 (quotation omitted).¹⁰

“To consider the matter from the point of view of another standing requirement, namely, redressability, makes clear that” there is no evidence that IWR’s injury is fairly traceable to the

¹⁰ Plaintiffs have erroneously relied on *Department of Commerce, et al. v. New York, et al.*, 139 S. Ct. 2551 (2019), for the proposition that they can speculate as to the purportedly predictable effect of government action on third parties. *See* Mot. Hr’g. Tr. at 20:1-3. But as the Supreme Court recently clarified, the *Commerce* “plaintiffs relied not only on ‘the predictable effect of Government action on the decisions of third parties’ but also on comprehensive studies, rather than mere ‘speculation.’” *California*, 141 S. Ct. at 2119 (quoting *Commerce*, 139 S. Ct. at 2565-66).

scope of federal entities covered by the 2020 Rule. *See California*, 141 S. Ct. at 2115. “To determine whether an injury is redressable, a court will consider the relationship between ‘the judicial relief requested’ and the ‘injury’ suffered.” *Id.* (quoting *Allen v. Wright*, 468 U.S. 737, 753 n.19 (1984)). Here, IWR seeks an order vacating the Rule’s construction of the scope of federal entities covered by Section 1557. Am. Compl. at p. 106. But that relief would only have an implication for IWR’s Abortion Fund expenditures if, in light of the vacatur, IHS would be likely to revert to a policy or practice it had in place prior to the effective date of the 2020 Rule, which, in turn, would be likely to lead to decreased calls and requests for funds from IWR. But because IHS has done nothing differently in light of the 2020 Rule’s scope of covered entities, *see* Woitte Decl. ¶¶ 7-11, an order vacating this portion of the rule would have no impact on IHS operations, and there is no reason to believe that IWR would see a reduction in call volume or Abortion Fund expenditures, *see Nat'l Wrestling Coaches Ass'n v. Dep't of Educ.*, 366 F.3d 930, 939-40 (D.C. Cir. 2004) (analyzing similar standing problems in the context of a challenge to Title IX guidance).

Contrast IWR’s failure to establish traceability or redressability with *Massachusetts*, 923 F.3d at 224. In that case, “the Commonwealth ha[d] demonstrated that it is highly likely that at least three [specific] employers in the Commonwealth”—Autocam Medical Devices, Hobby Lobby Stores, and Cummins-Allison Corporation—“will use the [challenged] expanded [contraceptive coverage requirement] exemptions[.]” *Id.* The Commonwealth demonstrated that if these three entities implemented a new policy—namely, declining to provide their employees contraceptive coverage—as would be permitted under the challenged regulation, the Commonwealth would be directly harmed in its capacity as secondary payor for contraceptive coverage under MassHealth. *Id.* Accordingly, a court order vacating or enjoining the challenged regulation would directly result in those three employers continuing to provide employees contraceptive coverage and the Commonwealth’s imminent harm—absorbing those costs as the default MassHealth secondary payor—would be redressed. Here, Plaintiffs establish no similar IHS policy change.

Accordingly, no IHS action is substantially likely because of a court order vacating this provision of the rule, so there is no reason that vacatur would impact IWR Abortion Fund expenditures.

E. Evidence of Certain Pregnancy-Related Coverage Exclusions is Not Evidence of any Plaintiff's Injury, Let Alone One Fairly Traceable to Anything in the 2020 Rule

Plaintiffs also gesture toward a number of health plans that purportedly do not provide pregnancy-related coverage for non-spousal dependent children. *See* ECF No. 56 at 6-7. But no Plaintiff has shown that it has been harmed by any of these policies. CrescentCare may well “provide[] healthcare services, including” certain types of pregnancy-related care, ECF No. 56 at 7, but there is no evidence that CrescentCare is experiencing less advantageous third-party reimbursement for medically necessary healthcare services than it had been receiving in the past. And the cited pregnancy-related coverage has nothing to do with the gender identity-related injuries that Plaintiffs alleged in the Amended Complaint or argued in response to HHS’s motion to dismiss.

Moreover, Plaintiffs provide no evidence that these benefit designs are *new* policy choices that have been taken *because* of anything in the 2020 Rule. *See Massachusetts*, 923 F.3d at 224 n.9. In fact, it has been reported that these type of benefit designs may have been widespread long before the 2020 Rule. *See* Megan Leonhardt, *This 24-year-old mistakenly thought her health insurance covered her pregnancy—and 4.2 million others like her may be at risk*, CNBC.com, Nov. 26, 2019 (attached as Exhibit 4).¹¹

In addition, Plaintiffs fail to identify any nexus between any challenged provision of the 2020 Rule and these benefit designs. To be sure, the 2020 Rule narrows the scope of insurers that are covered by Section 1557, but Plaintiffs admit that all of these plans continue to be “subject to Section 1557” under the 2020 Rule. *See* ECF No. 56 at 6. Moreover, since one district court “stay[ed] the repeal of the 2016 definition of discrimination on the basis of sex” from the Code of Federal Regulations, *see Asapansa-Johnson Walker*, 480 F. Supp. 3d 430, these policies could not

¹¹ Available at <https://www.cnbc.com/2019/11/26/when-your-insurer-does-not-cover-your-maternity-costs.html>

have been caused by HHS’s decision not to define “on the basis of sex” by rule. And in any event, as described *infra* at 16-17, impermissible pregnancy discrimination in benefit design continues to be prohibited under the 2020 Rule even if the *Asapansa-Johnson Walker* court lifted its preliminary injunction. *See* 85 Fed. Reg. 37,177 (“The Department will enforce vigorously Section 1557’s prohibition on the basis of disability against all covered entities, including when discrimination is alleged to have taken place in benefit design.”).

III. CONTRARY TO PLAINTIFFS’ ALLEGATIONS, PREGNANCY-RELATED DISCRIMINATION IS PROHIBITED UNDER THE 2020 RULE

Plaintiffs are wrong to argue that the 2020 Rule permits pregnancy-related discrimination by covered entities. During the motion hearing, the Court asked undersigned counsel: “Is it the position of HHS that discrimination on the basis of sex includes pregnancy-related discrimination?” Mot. Hr’g Tr. at 21:13-15. The answer is yes; Section 1557 provides that “an individual shall not, on the ground prohibited under . . . title IX of the Education Amendments of 1972 . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination” by certain covered entities. 42 U.S.C. § 18116(a). HHS’s decision not to include a definition of “on the basis of sex” in Section 1557 regulations does not narrow the scope of sex discrimination prohibited by the statute. In the preamble to the 2020 Rule, HHS explained that “[u]nder this final rule, the Department will interpret Section 1557’s prohibition on sex-based discrimination consistent with Title IX and its implementing regulations.” 85 Fed. Reg. at 37,192. HHS’s Title IX implementing regulations have long required that federal funding recipients “treat pregnancy, childbirth, false pregnancy, termination of pregnancy and recovery therefrom in the same manner and under the same policies as any other temporary disability with respect to any medical or hospital benefit, service, plan or policy which such recipient administers, operates, offers, or participates in . . .” 45 C.F.R. § 86.40(b)(4); *see also id.* § 86.21(c)(2) (admissions); *id.* § 86.57(b) (marital or parent status). Nothing in the 2020 Rule has any effect on those longstanding Title IX regulations implementing the statute that Congress referenced in Section 1557.

Plaintiffs point to a November 6, 2020, letter from OCR to the National Women’s Law Center advising the organization that it declined to investigate certain allegations of discrimination. ECF No. 56 at 8. But agencies enjoy wide prosecutorial discretion in addressing individual complaints in light of the “many variables involved in the proper ordering of its priorities.” *See Heckler v. Chaney*, 470 U.S. 821, 831-32 (1985). Because the letter does not state that HHS declined to investigate *because* sex discrimination excludes pregnancy-related discrimination, it is not probative of the answer to the Court’s question.

What is more, Plaintiffs’ reference to the letter serves only to highlight their lack of standing in this case as they may not invoke their “interests in enforcement” of Section 1557 by HHS as a basis of standing to seek vacatur of any part of the 2020 Rule. *See Diamond v. Charles*, 476 U.S. 54, 64 (1986). Plaintiffs cannot “compel [HHS] to enforce [its Section 1557 regulations] . . . because ‘a private citizen lacks a judicially cognizable interest in the prosecution or nonprosecution of another.’” *Id.* (quoting *Linda R.S. v. Richard D.*, 410 U.S. 614, 619 (1973)).

Title IX, and therefore Section 1557, prohibits discrimination on the basis of sex, including pregnancy-related discrimination. Removing an express mention of pregnancy discrimination from the Section 1557 regulations did not alter the scope of pregnancy discrimination the statutes prohibit.

IV. PLAINTIFFS LACK STANDING TO CHALLENGE THE 2020 RULE PROVISIONS ENJOINED FROM TAKING EFFECT BEFORE OCTOBER 2020

Plaintiffs continue to lack standing to challenge the 2020 provisions that were enjoined before taking effect. While Plaintiffs are in no better position now than they were earlier in this case to provide evidence to support their counterintuitive theories of standing with respect to the provisions of the 2020 Rule that other district courts have enjoined from taking effect, their allegations of injury from those changes have always been speculative. *See Washington*, 482 F. Supp. 3d at 1112-21. Moreover, Plaintiffs’ failure to provide evidence of concrete injury due to

any other provision of the 2020 Rule is probative of the fact that injuries from these changes were always speculative.¹²

Even if this Court disagrees or views “the constitutional standing issue to be a close one” (which it is not), “prudential reasons alone provide adequate basis” to dismiss these claims, *see McInnis-Misenor v. Me. Med. Ctr.*, 319 F.3d 63, 70, 73 (1st Cir. 2003), especially in light of events occurring since the change in presidential administrations. These events have strengthened Defendants’ motion to dismiss for lack of prudential ripeness.¹³ There is a likelihood that the several provisions of the 2020 Rule that have not taken effect because of nationwide preliminary injunction orders issued by other courts may never become effective.

Fitness. “[I]f a plaintiff’s claim, though predominately legal in character, depends on future events that may never come to pass, or that may not occur in the form forecasted, then the claim is unripe.” *Id.* (quoting *Ernst & Young v. Depositors Econ. Prot. Corp.*, 45 F.3d 530, 537 (1st Cir. 1995)). Here, (in addition to the typical reasons that all of Plaintiffs’ pre-enforcement claims seeking review of the regulations are unripe under standard administrative law principles, *see* ECF No. 22 at 24-30), “HHS has determined that it intends to initiate a [new] rulemaking proceeding on Section 1557[,]” which “will provide for the reconsideration of many or all of the changes to existing Section 1557 regulations that Plaintiffs challenge here.” ECF No. 49 at 2. Simultaneously, the courts that have issued preliminary injunctions have stayed proceedings “pending the new

¹² Due to the similarities between the repeal of the definition of “on the basis of sex,” which has been enjoined, and the conforming amendments to related regulations, which have not, Plaintiffs failure to produce any evidence of injuries fairly traceable to the latter change over the last ten months is especially probative as to lack of imminent injury due to the 2020 Rule’s repeal of the regulatory definition of “on the basis of sex.”

¹³ This case is one of five pending before various district courts challenging the 2020 Rule’s provisions. *See* ECF No. 51 at 3-4. On that basis alone, this Court is “well equipped” with discretion to dismiss this case without prejudice. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 155 (1967) (“A court may even in its discretion dismiss a declaratory judgment or injunctive suit if the same issue is pending in litigation elsewhere.”); *see also Black Warrior Riverkeeper, Inc. v. U.S. Army Corps. of Engr’s*, 781 F.3d 1271, 1290 (11th Cir. 2015) (“Undeniably, vacatur is equitable relief.”) (quotation omitted).

administration’s review of . . . the rule being challenged” during which time HHS “will continue to adhere to” the preliminary injunction orders. *See, e.g.*, Joint Motion for a Stay Proceedings, *Whitman-Walker Clinic, Inc. v. HHS*, No. 1:20-cv-01630-JEB, ECF No. 70 (D.D.C. Feb. 12, 2021), granted, Feb. 16, 2021. Accordingly, there is a substantial likelihood that the preliminary injunction orders will remain effective until HHS completes a new rulemaking proceeding that may well render Plaintiffs’ claims moot. Plaintiffs are seeking an advisory opinion about the validity of provisions of a rule that may never take effect (let alone harm any of them, if it ever did take effect). *See Belmont Abbey Coll. v. Sebelius*, 878 F. Supp. 2d 25, 39 (D.D.C. 2012) (Boasberg, J.) (holding that “a challenge to final regulations that Defendants have promised to amend” was not ripe for review even *without* preliminary injunctions).

Hardship. The hardship analysis for prudential ripeness is more stringent for plaintiffs than the standing analysis and “focuses on ‘direct and immediate’ harm [from delay]. It is unconcerned with wholly contingent harm.” *See McInnis-Misenor*, 319 F.3d at 73. Here, *at least* with respect to the preliminarily enjoined provisions of the 2020 Rule, there can be no suggestion that Plaintiffs could suffer hardship from delay if this Court were to issue a dismissal without prejudice to refiling in the event the preliminary injunctions are dissolved or HHS’s anticipated rulemaking proceeding does not address Plaintiffs’ policy concerns with the 2020 Rule. *See Belmont Abbey Coll.*, 878 F. Supp. 2d at 41 (“If Plaintiff is displeased by the ultimate regulations, it may certainly renew its suit at that time. All the Court holds here is that [plaintiff] has no basis to proceed now.”).

CONCLUSION

For the foregoing reasons, Plaintiffs’ supplemental evidence has failed to demonstrate that at the time they filed this suit they faced imminent injury fairly traceable to any provision of the 2020 Rule that they challenge. This Court should grant Defendants’ motion and dismiss the Amended Complaint.

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Respectfully submitted,

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